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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,620	09/24/2003	Daniel B. Roitman	10030589-1	5622

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[REDACTED] EXAMINER

JUNG, UNSU

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1641

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/669,620	ROITMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 August 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 5,15,19-28 and 30-33 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,6-14,16-18 and 29 is/are rejected.
- 7) Claim(s) 12 and 29 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/24/03 &amp; 2/23/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Applicants' preliminary amendments to the specification in the reply filed on February 17, 2004 have been acknowledged and entered
2. Applicants' amendments to claims 8, 9, 11, 13, 16, and 29 in the reply filed on August 23, 2006 have been acknowledged and entered.
3. Claims 1-33 are pending.

***Election/Restrictions***

4. Applicant's election of Group I (claims 1-19 and 29) and species election of polymeric material for List I, dielectric material for List II, symmetrical pattern for List III, color dyes for List IV, and surface opposing a first patterned surface; and a second embossed polymeric material having a second inner surface opposing a second patterned surface, wherein said first inner surface forms a bond with said second inner surface for List V in the reply filed on August 23, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-4, 6-14, 16-18, and 29 reflect the species election and are under consideration for their merits.

***Information Disclosure Statement***

5. The information disclosure statement filed on February 23, 2004 has been considered. However, the following corrections were made.

- Colburn et al. (Sheet 1 of 9): journal information as indicated on the IDS has been added
- Low-Surface-Energy Photoresist as a Medium for Optical Replication (Sheet 2 of 9): page numbers, "p82-85", and place of publication, "University of Rochester, Laboratory for Laser Energetics", have been added
- Assays, labeling, signaling & detection glossary (Sheet 4 of 9): "Assays" has been deleted
- All U.S. PG Pub. documents were moved to U.S. Patent document section

6. The information disclosure statement filed on February 23, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the references that have been lined through have not been considered as copies of the lined through references were not found in the parent application no. 10/379,107.

***Claim Objections***

7. Claim 12 objected to because of the following informalities: the word "where" should be corrected to "wherein" in line 1. Appropriate correction is required.
  
8. Claim 29 objected to because of the following informalities: the limitation of "creating a patterned master substrate having at least one pattern and at least one shape, the at least one pattern having at least one level of pattern depth, the at least one shape enabling identification and proper seating in a receiving substrate; applying polymeric material to the patterned master substrate to form at least one patterned polymeric microbead or at least one patterned microbead precursor; partitioning the polymeric material to form the at least one polymeric microbead; and releasing the polymeric material from the patterned master substrate" was not previously present in claim 29. The added limitation in the reply filed on August 23, 2006 should be underlined to indicate as such.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
  
10. Claims 1-4, 6-14, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. In claim 1, the term "means effectively associated" is vague and indefinite. The specification does not define term and it is unclear what the term "means effectively associated" means.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 2, 3, 7, 17, 18, and 29 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Ravkin et al. (U.S. Patent No. 6,908,737, Published on Jan. 9, 2003 and Filed on Oct. 19, 2000).

Ravkin et al. anticipates instant claims by teaching a microbead particle system for bioassay comprising:

- at least one microparticle made of polymeric material (column 23, lines 42-45);

- a pattern encoded on at least one portion of said at least one microbead particle (column 20, lines 49-67);
- a selected geometry effectively associated with said at least one microbead particle, said selected geometry capable, alone or with other artifacts, of identifying at least microbead particle (column 20, lines 49-67); and
- means effectively associated with said at least one microbead particle for enabling or enhancing chemical conjugation between said at least one microbead particle and a ligand (column 22, lines 46-67).

With respect to claim 2, Ravkin et al. teaches a microbead particle system, wherein the said polymeric material is organosilicon resins (column 15, lines 22-30).

With respect to claim 18, Ravkin et al. teaches a microbead particle system, further comprising means for marking said at least one microbead particle after binding with an analyte, said at least one microbead particle being identified by the emission of dyes or luminescent molecules associated with the analyte (column 27, lines 3-11).

With respect to claim 7, Ravkin et al. teaches a microbead particle system, wherein the pattern is symmetrical (Fig. 10B).

With respect to claim 17, Ravkin et al. teaches that teaches a microbead particle system, further comprising a first embossed polymeric material having a first inner surface opposing a first patterned surface and a second embossed polymeric material having a second inner surface opposing a second patterned surface, wherein the first

inner surface forms a bond with the second inner surface (column 10, lines 61-65 and Fig. 14).

According to the current specification (p5), the microbead particle of claim 1 formed by the method recited in claim 29. MPEP states that the lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

14. Claims 4 and 6 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Ravkin et al. (U.S. Patent No. 6,908,737, Published on Jan. 9, 2003 and Filed on Oct. 19, 2000) in light of Kolesar, Jr. et al. (U.S. Patent No. 4,906,440, Mar. 6, 1990).

Ravkin et al. teaches a microbead particle system for bioassay as discussed above. Further, Ravkin et al. teaches a microbead particle system further comprising at

least one layer of material, silicon nitride (column 15, lines 33-38) on polymeric material. However, Ravkin et al. fails to teach that the one layer of material is dielectric material. Kolesar, Jr. et al. teaches that silicon nitride is a dielectric material (column 8, line 8). Therefore, one of ordinary skill in the art would have realized that the microbead particle system of Ravkin et al. comprising a silicon nitride layer is a dielectric material.

With respect to claim 6, Ravkin et al. teaches a microbead particle system, wherein said at least one layer of material includes at least one surface suitable for chemical conjugation with a ligand (column 22, lines 46-67).

#### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 8-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravkin et al. (U.S. Patent No. 6,908,737, Published on Jan. 9, 2003 and Filed on Oct. 19, 2000) in view of Tompkin et al. (U.S. Patent No. 5,754,520, May 19, 1998).

Ravkin et al. teaches a microbead particle system for bioassay as discussed above. However, Ravkin et al. fails to teach a microbead particle system, wherein the pattern encoded on at least one portion of the microbead particle generates a diffractive image.

Tompkin et al. teaches a method of using diffraction grating patterns as optical data carriers (Abstract). In the simplest case, the diffraction pattern is a diffraction grating with a symmetrical or asymmetrical profile shape, which diffracts light predominantly in two or single direction, respectively (column 12, lines 1-4). Diffraction pattern of one profile shape (one unit cell) can represent value "1" and the other

(second unit cell) can represent "0" so that information can be stored in multiple number of unit cells, which represents a plurality of bits (column 12, lines 1-40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the optical coding method of Tompkin et al., which comprises use of symmetrical and asymmetrical diffraction grating patterns that are capable of generating diffractive images, in the microbead particle system of Ravkin et al. in order to use binary code to encode the microbead particle system. Combining diffraction grating coding method of Tompkin et al. with the coding methods of Ravkin et al. is advantageous as additional coding method would provide increased repertoire of different types of codes to distinguish the microbead particle system of Ravkin et al. with a reasonable expectation of success as the methods of generating and reading diffraction grating pattern is done on polymeric surface is well known in the art of optical coding applications.

With respect to the recitation of claims 8-10, "wherein said pattern is capable of generating a diffractive image", generating a diffractive image is an inherent property of diffraction grating patterns of Tompkin et al. upon illumination.

With respect to claim 9, Tompkin et al. teaches a diffraction grating pattern comprising at least one unit cell, which is being repeated (column 12, lines 1-40).

With respect to claim 11, Tompkin et al. teaches a diffraction grating pattern comprising plurality of regions (unit cell), which is capable of producing a plurality of electromagnetic responses.

With respect to the recitation of claims 11 and 12 "wherein said pattern is capable of producing a plurality of electromagnetic responses, wherein the plurality of electromagnetic responses is selected from the group consisting of reflectivity, light absorption, and photoluminescence", producing a plurality of electromagnetic responses such as reflectivity, light absorption, and photoluminescence is an inherent property of diffraction grating patterns of Tompkin et al. upon illumination an electromagnetic source.

With respect to claim 13, Ravkin et al. teaches a pre-selected geometry associated with the microbead particle (column 20, lines 35-40). With respect to the recitation of "wherein the said geometry enables seating in a receiving substrate in a manner effective for particle identification", enabling seating in a receiving substrate in a manner effective for particle identification is an inherent property of the pre-selected geometry associated with the microbead particle.

With respect to claim 14, Ravkin et al. teaches that the pre-selected surface shape and size is triangles, circles, or squares (column 5, lines 49-56), wherein said pre-selected surface shape is used in combination with color dyes (column 9, lines 43-44). With respect to the recitation of "said treatment creating an interferometric or holographic color pattern", creating an interferometric or holographic color pattern is an inherent property of said pre-selected surface shape with color dye treatment.

With respect to claim 16, Tompkin et al. teaches that the pattern represents ridges and troughs (Fig. 5) corresponding to constructive and destructive interference patterns. With respect to the recitation of "a relationship between said ridges and

troughs being a function of refractive index of said polymeric material, refractive index of a medium through which the depth of said pattern is measured, and the wavelength of light impinging on said pattern", the ridges and troughs being a function of refractive index of said polymeric material, refractive index of a medium through which the depth of said pattern is measured, and the wavelength of light impinging on said pattern is an inherent property of the polymeric material of the microbead particle having patterns of ridges and troughs.

### ***Double Patenting***

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Copending Application No. 10/379,107

Claims 1-13 and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/379,107. Although the conflicting claims are not identical, they are not patentably distinct from each other because each teach a microbead particle system for bioassay comprising:

- at least one microparticle made of polymeric material;
- a pattern encoded on at least one portion of said at least one microbead particle;
- a selected geometry effectively associated with said at least one microbead particle, said selected geometry capable, alone or with other artifacts, of identifying at least microbead particle; and
- means effectively associated with said at least one microbead particle for enabling or enhancing chemical conjugation between said at least one microbead particle and a ligand.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 14, 17, and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/379,107 in view of Ravkin et al. (U.S. Patent No. 6,908,737, Published on Jan. 9, 2003 and Filed on Oct. 19, 2000).

The copending Application teaches a microbead particle system for bioassay as discussed above. However, the copending Application fails to teach a microbead particle system, wherein the pre-selected surface shape and size is selected from the group consisting of triangles, circles, squares, crosses, diamonds, parallelograms, and semicircles, wherein said pre-selected surface shape is used in combination with a treatment is color dyes.

Ravkin et al. teaches a microbead particle system for bioassay as discussed above. Ravkin et al. further teaches a microbead particle system, wherein the pre-selected surface shape and size includes triangles, circles, or squares (column 5, lines 49-56) in combination with color dyes (column 9, lines 43-44), which can be used as coding materials (column 10, lines 7-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ pre-selected surface shape and size include triangles, circles, or squares in combination with color dyes as a coding scheme in the microbead particle system of copending Application in order to achieve greater information content with fewer coding positions. The advantage of additional coding scheme to achieve greater information content with fewer coding positions provides the motivation to combine teachings of the copending Application and Ravkin et al. with a reasonable expectation of success.

Claim 16 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/379,107 in view of Tompkin et al. (U.S. Patent No. 5,754,520, May 19, 1998).

The copending Application teaches a microbead particle system for bioassay as discussed above. However, the copending Application fails to teach a microbead particle system, wherein the pattern represents ridges and troughs corresponding to pre-selected constructive and destructive interference patterns.

Tompkin et al. teaches a method of using diffraction grating patterns as optical data carriers as discussed above. Tompkin et al. further teaches that the pattern represents ridges and troughs (Fig. 5) corresponding to constructive and destructive interference patterns.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the optical coding method of Tompkin et al., which comprises use of symmetrical and asymmetrical diffraction grating patterns representing ridges and troughs that are capable of generating diffractive images, in the microbead particle system of the copending Application in order to use binary code to encode the microbead particle system as the use of symmetrical and asymmetrical diffraction grating patterns representing ridges and troughs provides a simple method of generating binary codes.

This is a provisional obviousness-type double patenting rejection.

***Prior Art of Record***

21. The following prior art made of record and not relied upon are considered pertinent to applicant's disclosure.

- Ravkin et al. (U.S. PG Pub. No. US 2003/0129654 A1, Filed Oct. 18, 2002) teaches code particles for multiplexed analysis (entire document).
- Som et al. (WO 01/78889 A2, Oct. 25, 2001) teaches method of fabricating coded particles for use in chemical or biological library synthesis (entire document).

***Conclusion***

22. No claim is allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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